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(Cela)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/193,538 11/17/98 BILLING-MEDEL P 6193.US.P1

023492  
ABBOTT LABORATORIES  
DEPT. 377 - APED-2  
100 ABBOTT PARK ROAD  
ABBOTT PARK IL 60064-6050

HM22/0803

EXAMINER

SOLAYA, T

ART UNIT

PAPER NUMBER

1655  
DATE MAILED:

17

08/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Advisory Action</b>	Application No. <b>09/193,538</b>	Applicant(s) <b>Billing-Medel et al</b>
	Examiner <b>Jehanne Souaya</b>	Art Unit <b>1655</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED Jul 16, 2001 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a)  The period for reply expires 5 months from the mailing date of the final rejection.
- b)  In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.  A Notice of Appeal was filed on Mar 16, 2001. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2.  The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.
3.  The proposed amendment(s) will not be entered because:
  - (a)  they raise new issues that would require further consideration and/or search. (See NOTE below);
  - (b)  they raise the issue of new matter. (See NOTE below);
  - (c)  they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d)  they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

4.  Applicant's reply has overcome the following rejection(s):
   
\_\_\_\_\_  
\_\_\_\_\_
5.  Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).
6.  The a)  affidavit, b)  exhibit, or c)  request for reconsideration has been considered but does NOT place the application in condition for allowance because:
   
see attachment
  
\_\_\_\_\_
7.  The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
8.  For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):
   
Claim(s) allowed: none
  
Claim(s) objected to: none
  
Claim(s) rejected: 52-78
  
\_\_\_\_\_
9.  The proposed drawing correction filed on \_\_\_\_\_ a)  has b)  has not been approved by the Examiner.
10.  Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
11.  Other:

## ATTACHMENT

The amendment filed July 16, 2001 will be entered upon the timely filed submission of an Appeal Brief. Applicant's notice of appeal has been entered into the instant application. Upon entry of the amendment filed July 16, 2001, claim 52-78 will be pending. The rejections (under 35 USC 101 and 35 USC 112/first paragraph) of the previous claims 1-13, 15-22, 38, 41, and 45-49 are maintained with respect to the newly added claims for the following reasons:

With regard to 35 USC 101 rejection:

Applicant's traverse on the grounds that the examples and methods disclosed in the specification are useful for detecting at least, breast diseases that may be detected using gene markers and related gene marker technology. Applicants further state that a protein or nucleic acid may be useful in diagnosis or prognosis of a patient's disease status and cites HER-2-neu and estrogen receptor protein as examples. These arguments have been thoroughly reviewed but were found unpersuasive because, as stated in previous office actions, the specification does not demonstrate such a diagnostic utility. Indeed, the specification teaches that BS274 was found in non-breast libraries. Furthermore, while it is known in the art that PSA levels are elevated in prostate cancer, such an extrapolation cannot be made for BS274 as there is no teaching in the specification or the art that even suggest that BS274 and PSA are homologous, or have similar modes of action in cancer, or have similar functions, etc. Likewise, one cannot extrapolate that because CEA is found in blood at elevated levels in colorectal cancer, that the presence of BS274 outside breast tissue indicates a form of breast disease. While this could be an indication of breast disease, the specification has not shown that it is. The specification has only asserted that it is based on such characteristics of known cancer specific markers that are in no way related to BS274. Although such characteristics are established for other cancer markers, one cannot

assume that such is the case for BS274 without a correlation of BS274 with breast disease, which the specification and the art fail to teach.

With regard to 35 USC 112/first paragraph:

The enablement and written description rejections are maintained on the grounds that the newly added claims are drawn methods or products with language drawn to a sequence "having" a specific sequence or to sequences "encoding" an epitope or to sequences "comprising" a specific SEQ ID NO. As stated in previous office actions the claims broadly encompass full genes, genomic sequences which have not been described. The term "having" is considered "open" terminology unless the specification makes clear that such language is drawn to "closed" terminology.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Jehanne Souaya*  
Jehanne Souaya  
Patent examiner

*August 1, 2001*

*Carla Myers*  
CARLA J. MYERS  
PRIMARY EXAMINER